

King, Valerie A.

From: King, Valerie A.
Sent: Thursday, July 18, 2002 6:09 PM
To: 'Ortrun.Presting@parexel.com'
Cc: Oey, Jan
Subject: Changes to Informed Consent

Ortrun:

Since Jan was traveling today, he asked that I forward you the changes we would like to make to the informed consent for the JLI menthol study. They are as follows:

- ✓ Page 2 - First bullet point ("You have not smoked Marlboro Ultra Lights Menthol,..."); Change to read: You have not smoked Marlboro Ultra Lights Menthol as your exclusive brand without interruption for 4 weeks prior to study initiation.
- Page 3 - Second to last paragraph, last sentence: Change to read: One group will be allowed to smoke the study cigarettes (ACCORD JLI Menthol) using the special lighter that allows you to get up to 8 puffs per cigarette.
- ✓ Page 3 - Last paragraph, third sentence: Should be changed to read: Subjects who elect to quit smoking may do so and may choose to continue in their assigned smoking group and finish the study according to that group's schedule.
- ✓ Page 4 - Second paragraph: Delete last sentence "If you withdraw from the study at any time, the standard of care that you receive from the clinic will not change."
- ✓ Page 4 - Third paragraph, line 10: Delete the "any" in the words "...blood test which the ~~any~~ other routine chemistry...."
- ✓ Page 5 - First sentence: Change to read, "...smoke Marlboro ULTRA LIGHTS Menthol until 11 pm that evening, which will be provided by the clinic upon request to the study staff."
- ✓ Page 5 - Third paragraph, second sentence: change to read, "...Marlboro ULTRA LIGHTS Menthol until 11 pm that evening and the study staff..."
- Page 5 - Third paragraph, last two sentences: Replace with, "You will be allowed to smoke a maximum number + 20% of cigarettes that you reported in your smoking history at Screening up to a maximum number of 30 cigarettes per day."
- ✓ Page 5 - 7th paragraph, second sentence: Replace "visualize" with "visually examine"
- Page 7 - 2nd paragraph, second sentence: Change to read, "If this occurs, the Principal Investigator will talk to you."
- ✓ Page 7 - 6th paragraph, line 6: Replace "your medical" with "the study"
- Page 8 - 1st paragraph, line 4: Replace "study doctor" with "Principal Investigator" - NOTE - this should be a global change through the ICF for consistency.
- ✓ Page 9 - Second paragraph, line 6: insert "and that I have no known existing undisclosed medical problems" after "years of age"

If you have questions about any of the above changes, please let me or Jan know.

Thanks,
Valerie